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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte H. WILLIAM BOSCH, KEVIN D. OSTRANDER,
and EUGENE R. COOPER

Appeal 2011-002039
Application 10/697,716
Technology Center 1600

Before TONI R. SCHEINER, ERIC GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a pharmaceutical composition, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 1-3, 5-7, 9-14, 17-21, 28-41, and 43-47 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 is representative and reads as follows:

1. A composition comprising:

(a) particles of at least one triamcinolone or a salt thereof, wherein the triamcinolone particles have an effective average particle size of less than about 2000 nm and have a phase selected from the group consisting of crystalline, amorphous, and semi-crystalline; and

(b) at least one surface stabilizer absorbed on the surface of the triamcinolone particles, wherein said surface stabilizer is a surfactant.

The Examiner has rejected claims all of the claims on appeal under 35 U.S.C. § 103(a) based on Liversidge[1] and Desai[2] (Answer 5[3]). The Examiner finds that Liversidge discloses particles that do not include triamcinolone but otherwise meet the limitations of claim 1 (*id.* at 5-6). The Examiner concludes that modifying Liversidge's particles to include triamcinolone would have been obvious because Liversidge discloses that its particles can be made with a variety of poorly water-soluble drugs, including corticosteroids, and Desai discloses that triamcinolone is a poorly water-soluble corticosteroid (*id.* at 7-8).

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[1] Liversidge et al., US 5,145,684, Sept. 8, 1992.

[2] Desai et al., US 5,916,596, June 29, 1999.

[3] In addition to the rejection based on obviousness, the Office Action mailed Sept. 15, 2009 included twenty provisional rejections for obviousness-type double patenting. In the Answer, the Examiner expressly withdrew two of the provisional rejections (Answer 4) and did not present any of the others as "Grounds of Rejection" (*see* Answer 5-9). We therefore understand all of the provisional rejections to have been withdrawn. *See* MPEP § 1207.02(A)(9) (The Answer is required to include "[f]or each ground of rejection maintained by the examiner . . . , an explanation of the ground of rejection."). In the event that the Examiner did not intend to withdraw the eighteen provisional rejections that were not expressly withdrawn, we vacate them because the Answer does not provide any basis for concluding that the claims on appeal are obvious variants of the claims in the copending applications. *See* MPEP § 1207.02(A)(9)(f) ("For each rejection . . . the examiner's answer must specifically explain the basis for the particular rejection.")

Appellants contend that to obtain the claimed composition "one skilled in the art first has to choose the drug category of corticosteroids out of 40 categories of drugs disclosed by Liversidge . . . , and then among all corticosteroids, select triamcinolone. Neither of the cited references provides any guidance to make the specific selection." (Appeal Br. 18.) Appellants also contend that the evidence shows unpredictability in the art and therefore does not support a reasonable expectation of success (*id.* at 19-20; Reply Br. 11-12).

The issue presented is: Would a person of ordinary skill in the art have considered it obvious to include triamcinolone in Liversidge's particles with a reasonable expectation of success?

Findings of Fact

1. Liversidge discloses "[d]ispersible particles consisting essentially of a crystalline drug substance having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 400 nm" (Liversidge, abstract).

2. Liversidge discloses that "[p]referred surface modifiers include nonionic and anionic surfactants" (*id.* at col. 4, ll. 38-39).

3. Liversidge discloses that its "invention can be practiced with a wide variety of drug substances. . . . The drug substance must be poorly soluble and dispersible in at least one liquid medium. . . . A preferred liquid dispersion medium is water." (*Id.* at col. 3, ll. 38-46.)

4. Liversidge discloses that "[s]uitable drug substances can be selected from a variety of known classes of drugs including, for example, . . . corticosteroids" (*id.* at col. 3, ll. 53-64).

5. Liversidge discloses that its "particles can be formulated into pharmaceutical compositions exhibiting remarkably high bioavailability" (*id.* at col. 2, ll. 34-36).

6. Desai discloses that "[s]ubstantially water insoluble pharmacologically active agents" (Desai, col. 11, ll. 17-18) include "corticosteroids (e.g., triamcinolone, . . . [and] triamcinolone acetonide . . .)" (*id.* at col. 14, ll. 13-17).

Analysis

Liversidge discloses particles with an effective average size of less than 400 nm that consist essentially of a crystalline drug having a surface modifier, preferably a surfactant, adsorbed on the surface. Liversidge discloses that a "wide variety" of poorly water-soluble drugs can be used in its particles, including corticosteroids. Desai discloses that triamcinolone and triamcinolone acetonide are substantially water-insoluble corticosteroids. We agree with the Examiner that these disclosures would have made it obvious to a person of ordinary skill in the art to practice Liversidge's invention using triamcinolone in order to achieve the "remarkably high bioavailability" disclosed by Liversidge.

Appellants argue that neither of the references suggests specifically selecting corticosteroids out of the forty categories of drugs suggested by Liversidge, or specifically selecting triamcinolone from among the corticosteroids (Appeal Br. 18).

This argument is unpersuasive, because Liversidge discloses that its particles provide high bioavailability and that a wide variety of poorly water-soluble drugs are suitable for use in them (FFs 3, 5). Thus, it would have

been obvious to combine a known poorly water-soluble drug – such as the triamcinolone disclosed by Desai – with Liversidge's particles in order to gain the resulting bioavailability. The fact that the instant claims are limited to only one of the obvious choices does not make that choice any less obvious. *See Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (The disclosure in the prior art of "a multitude of effective combinations does not render any particular formulation less obvious. This is especially true because the claimed composition is used for the identical purpose taught by the prior art.")

Appellants also argue that the art shows unpredictability in achieving a stable nanoparticulate composition because "Liversidge explicitly teaches that not every combination of active agent and surface stabilizer can produce a stable nanoparticulate active agent composition (column 7, lines 21-23, comparative examples A-F)" (Appeal Br. 19).

This argument is also unpersuasive. First, "comparative examples" are, by definition, for comparison to examples representing the invention. Liversidge's comparative examples resulted in particles that aggregated but Liversidge does not describe any of the examples representing its inventive particles as unsatisfactory (*see* Liversidge, col. 8, l. 35 to col. 13, l. 52). Liversidge's comparative examples therefore do not cast doubt on the expectation that using triamcinolone in Liversidge's particles would be successful.

In addition, although Liversidge states that "not every combination of surface modifier and drug substance provides the desired results" (Liversidge, col. 7, ll. 21-23), "[o]bviousness does not require absolute

predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). Liversidge supports a *reasonable* expectation of successfully making its particles with triamcinolone because it names corticosteroids as a specific category of drugs suitable for use in its particles, it names surfactants as preferred surface modifiers, and it discloses "a simple screening process whereby compatible surface modifiers and drug substances can be selected" (Liversidge, col. 7, ll. 24-26). Appellants have pointed to no evidence showing that a person of ordinary skill in the art would not have reasonably expected success in making Liversidge's particles with triamcinolone.

Finally, Appellants argue that the Examiner's rejection relies on improper obvious-to-try reasoning (Appeal Br. 20, Reply Br. 12-13). This argument is also unpersuasive. Appellants cite *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009), as supporting their position, but that case says that an example of an improper obvious-to-try reasoning is where "what would have been 'obvious to try' would have been to . . . try each of numerous possible choices . . . *where the prior art gave . . . no direction as to which of many possible choices is likely to be successful*." *Id.* at 1359 (emphasis added). Here, by contrast, Liversidge expressly discloses that its particles can be made using a "wide variety" of poorly water-soluble drugs (FF 3), supporting an expectation that any such choice is likely to be successful. The claimed combination thus would have been not just obvious to try but obvious under the standard of 35 U.S.C. § 103.

Conclusion of Law

A person of ordinary skill in the art would have considered it obvious to include triamcinolone in Liversidge's particles, and would have had a reasonable expectation of success.

SUMMARY

We affirm the rejection of claims 1-3, 5-7, 9-14, 17-21, 28-41, and 43-47 under 35 U.S.C. § 103(a) based on Liversidge and Desai.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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